# DEVICE DETAILS

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| **NAME OF DEVICE** | PULSE OXIMETER AND PROBE |
| **ESTABLISHMENT NAME** | CYPRESS MEDIC SDN BHD |
| **ROLE OF ESTABLISHMENT** | AUTHORIZED REPRESENTATIVE |
| **REGISTRATION NO** | GC6997520-40138 |
| **BRAND NAME** | ROSSMAX |
| **MEDICAL DEVICE CATEGORY** | MD 1300 - MONITORING DEVICES |
| **DEVICE GROUPING TYPE** | FAMILY |
| **DEVICE DESCRIPTION** | Rossmax Pulse Oximeter is used to measure arterial oxygen saturation (%SpO2) of hemoglobin and pulse rate, an important indicator of respiratory function. The model of pulse oximeter, only for SA300, has an ACT analysis function. ACT (Artery Check Technology) analyzes the pulse and SpO2 signals and determines the actually prevailing stiffness of the artery (Artery Condition). It further classifies the vascular status into 6 levels. Rossmax probe combined with pulse oximeter is to spot-check oxygen saturation in blood (SpO2) and pulse rate. |
| **DEVICE INTENDED PURPOSE** | SA Series: Rossmax Handheld Pulse Oximeter is used to measure oxygen saturation in blood(SpO2) and pulse rate, also to issue warnings immediately. The model of handheld pulse oximeter, only for SA300, has an ACT (Artery Check Technology) analysis function that analyzes the pulse and SpO2 signals and determines the actually prevailing stiffness of the artery (Artery Condition). It is a non-invasive device intended for spot-check of adults,child, and infants with corresponding probe applied at home, hospital and clinics. The probe contains a dual light source and a photo detector. Probe: The probe combined with pulse oximeter is to spot-check oxygen saturation in blood(SpO2) and pulse rate. The different probes combined with pulse oximeter is used on adults, neonatal, pediatric at hospital, clinics, and/ or home. |
| **VALIDITY DATE OF REGISTRATION** | 06/01/2020 - 05/01/2025 |

# LIST OF DEVICE

| NO | NAME OF DEVICE | IDENTIFIER |
|---|---|---|
| 1 | Pulse Oximeter | SA210 |
| 2 | Pulse Oximeter | SA310 |
| 3 | Pulse Oximeter | SA300 |
| 4 | Probe | PA100 |
| 5 | Probe | PB100 |

| NO | NAME OF DEVICE | IDENTIFIER |
|---|---|---|
| 6 | Probe | PC100 |
| 7 | Probe | PD100 |
| 8 | Probe | PF100 |